CUSTOMER REPORT

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Field study of microbicidal efficacy of Biovitae® lights

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Confidentiality: Confidential

Report's title

Field study of microbicidal efficacy of Biovitae® lights

Customer, contact person, address	**Order reference**
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Project name	**Project number/Short name**
BluelightStage3	124170

Summary

The aim of this study was to measure the microbicidal efficacy of Biovitae® lighting devices at first aid hospital of Rome's airport Fiumicino (co-operation with ADR Aeroporti di Roma Spa). The evaluation was based on comparison of the trend of the total bacteria count of samples taken from different surfaces both before and after the installation of the Biovitae® lighting systems.
According to the numbers of samples in each hygiene category the use of Biovitae® light has reduced numbers of sampling places with poor hygiene from 32.5% to 12.5% and the number of sampling places showing good hygiene has increased from 40% to 82.5% after Biovitae light installation.

Espoo, 11.10.2019

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Distribution (customer and VTT)

Customer (Rosario Valles) and VTT (archive, Satu Salo)

1. Description and objectives

The aim of this study was to measure the microbicidal efficacy of Biovitae® lighting devices in real environment. The *in vivo* study was performed at first aid hospital of Rome's airport Fiumicino. The goal was the evaluation of the trend of the total bacterial count through samples taken from different surfaces both before and after the installation of the Biovitae® lighting systems.

Customer was responsible of arranging the sampling and sending the samples to VTT for microbiological analysis and reporting. The sampling was planned to be performed for each surface twice before installing Biovitae® lighting systems and 4 times after the installation. Twenty surface spots was selected for sampling together with customer (table 1).

Table 1. List of sampling places in the emergency rooms of the Leonardo da Vinci airport (Fiumicino, Italy)

	SAMPLING SITE			
Sample identi-fication	**Room**		**Site**	**Height (meters) ***
A1	L1	Main entrance	Shelf	1.64
A2			Shelf	1.64
B1	L1	Registering station	Desk	1.97
B2			Desk	1.97
C1	L3	First-aid station	Doctor's desk (external side)	1.99
C2			Doctor's desk (external side)	1.99
C3			Doctor's desk (internal side)	1.99
C4			Doctor's desk (internal side)	1.99
C5			Examination bed	1.95
C6			Examination bed	1.95
D1	L9	Patient's recovery room	Patient's bed Table	1.69
D2			Patient's bed Table	1.69
D3			Patient's handle	1.39
D4			Patient's bed rails	1.79
D5			Patient's bed rails	1.79
E1	L4	Reporting room	PC Keyboard	1.96
E2			PC Monitor	1.96
E3			Sphygmomanometer	1.96
F1	L22	Doctor's Room	Doctor's desk	1.96
F2			Doctor's desk	1.96

* Height: the distance of the sampling site from the ceiling, measured by the means of a laser meter.

The description of rooms is following (provided by the customer):

L1 Main Entrance
The main entrance is accessed from the external space through an automated sliding glass door. It is the first area you come across when accessing the Hospital, where patients are registered from the staff. The patients, the ambulance crew that responded to the emergency call, and any companion must stop here. After only patients and crew come inside.

L1 Registering Station
In this room the operators register the patients before letting them go into the first aid station, in which they are brought by the ambulance crew. A glass windows separates this room from the main entrance.

L3 First Aid Station

In this room the patients access for the first clinical evaluation, and it can also be used for any minor surgical emergency. Inside the room there is the examination bed used for all medical assessments when the patient is awake and cooperative and doctor's desk.

L9 Recovery room
In this room are hosted patients who, after having been stabilized, require staying under observation for short a period of time (48 hours maximum). The presence of a companion is allowed.

L4 Reporting room
This room communicates directly with the first-aid station **(L3)** through a door. It hosts the devices for monitoring the most common vital functions (e.g. sphygmomanometer, ECG, etc.) and the PC is used by the medical and nursing staff to record the clinical activities performed on each patient.

L22 Doctors' room
This room is for exclusive use of the medical staff. Doctors use it both for resting and consuming meals.

2. Methods

Samples were taken at noon by customer's laboratory technician on 9.7.2019; 17.7.2019; 22.7.2019; 24.7.2019 and 30.7.2019. Swabs were sent to VTT and they were cultured on 11.7.2019; 23.7.2019; 24.7.2019; 26.7.2019 and 2.8.2019, respectively. Samples were taken from surfaces with sterile swabs, which were moistened with sterile water. Sampling area was 10 cm x 10 cm and disposable sterile mask was used to measure the area. Only exception was the pc board from which 10 different frequently used keyboard button was swabbed.

At VTT, microbes from the swabs were diluted to 4 ml of salt water containing peptone before traditional culturing on Plate Count agar plates (PCA) and Chromocult Coliform agar plates. Pour plate technique was used for determination of total bacteria on PCA in order to get detection limit 4 CFU(colony forming units)/100 cm^2. Coliforms were cultured using spreading technique on Chromocult agar plates with detection limit 40 CFU/100 cm^2. Incubation was performed for PCA-plates at 30°C for 3 d and for Chromocult -plates at 37°C for 2 d. After incubation period colonies were counted from the agar plates.

3. Results

Total bacteria counts from samples were from < 4 cfu/100 cm² to 2000 cfu/100 cm². From all 120 samples 59 samples were below 4 cfu/100cm² and two samples exceeded 2000 cfu/cm². For calculations samples with less than 4 cfu are counted as 4 cfu and samples exceeding 2000 cfu are counted as 2000 cfu. Total bacteria counts are presented in Figures 1 and 2.

Coliforms were detected only from 3 samples; 2 of them were from samples before Biovitae lights were installed and one after installation.

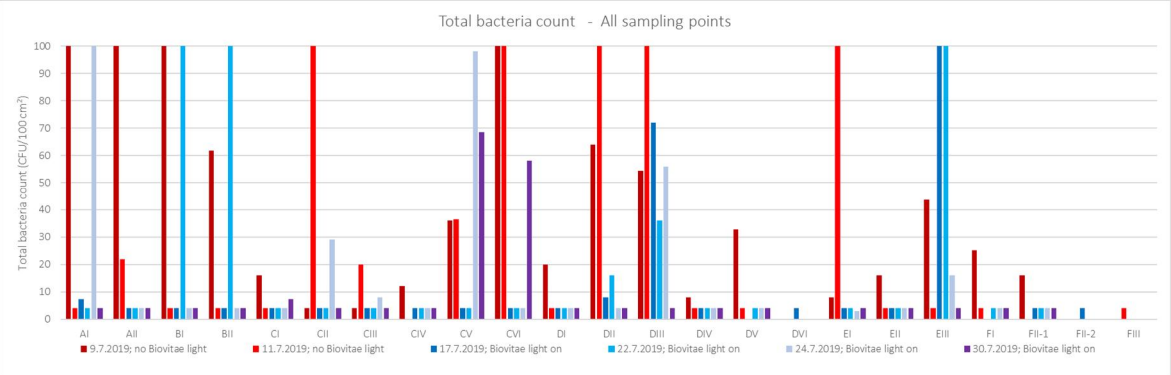

Figure 1. Total bacteria count by sampling points; some of the bars continue above 100 cfu/100 cm² but are shown here only to 100 cfu/cm². Detection limit 4 cfu/cm².

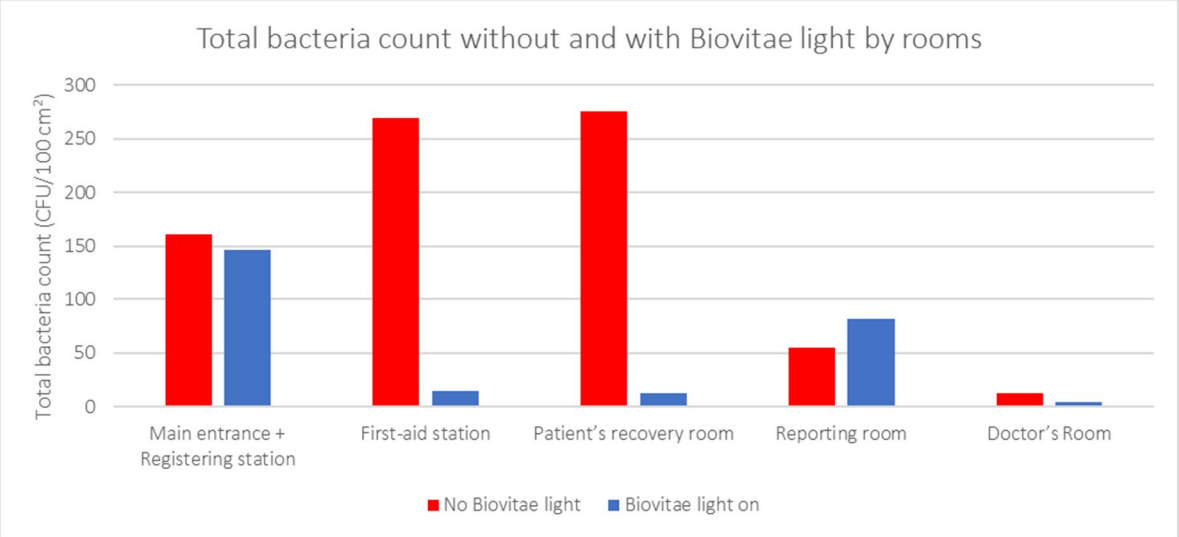

Figure 2. Average trend of the total bacteria count. The red bars represent the total bacteria count measured on the surfaces before installing the BIOVITAE® lighting devices; the blue bars represent the total bacteria count measured on surfaces after installing the BIOVITAE® lighting devices. Detection limit 4 cfu/cm².

4. Conclusions

In VTT's previous hospital studies we have defined for aerobic heterotrophic bacteria threshold limit <12 CFU/100 cm² for good result at hospital environmental surface with possible patient contact and 12-40 CFU/100 cm² for inadequate and >40 for poor hygiene (Wirtanen et al. 2012). The amounts of sampling places including to each hygiene category are shown in Table 2. According to the numbers of samples in each hygiene category the use of Biovitae light has reduced numbers of sampling places with poor hygiene from 32.5% to 12.5% and the number of sampling places showing good hygiene has increased from 40% to 82.5% after Biovitae light installation.

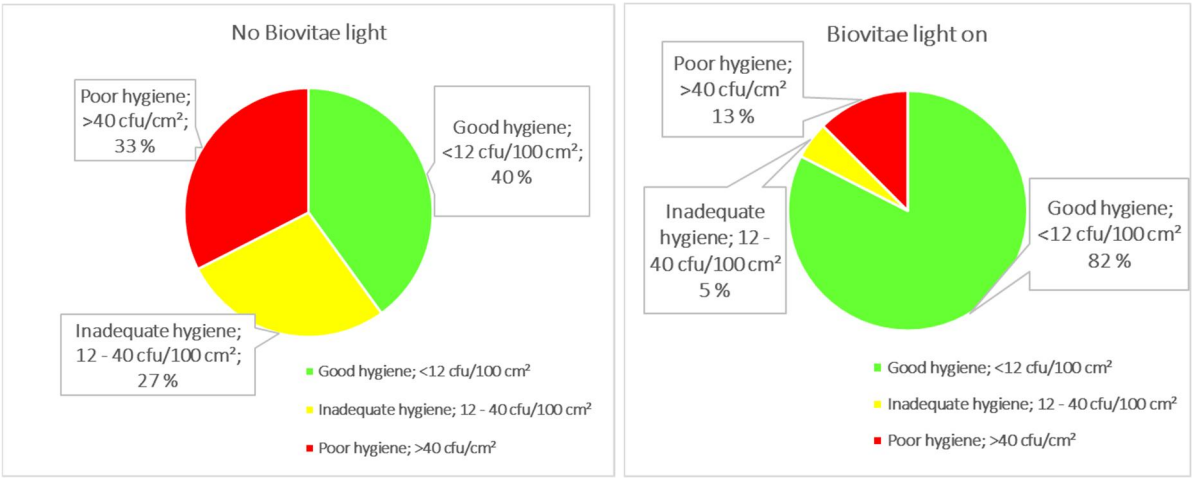

Figure 3. The amounts of sampling places included to different hygiene category percentually. Categories according to results from hospital environmental surface studies previously performed at VTT (Wirtanen, G., Nurmi, S., Kalliohaka, T., Mattila, I., Heinonen, K., Enbom, S., Salo, S. & Salmela, H. 2012. Surface and air cleanliness in operating theatre environments. Eur. J. Parent. Pharmaceut. Sci. 17:3, pp. 87-93).

References

Wirtanen, G., Nurmi, S., Kalliohaka, T., Mattila, I., Heinonen, K., Enbom, S., Salo, S. & Salmela, H. 2012. Surface and air cleanliness in operating theatre environments. Eur. J. Parent. Pharmaceut. Sci. 17:3, pp. 87-93